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Mail Stop Amendment Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Patent Application Serial No. 10/788,779

For: A Method for Detecting Disease Associated Mutations

Inventors: Christine E. Seidman et al.

Filed: February 27, 2004

Our Reference No. IGI-111CN2

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. PTO Form SB/08: and
- 3. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on: Elizabeth A. Hanley, Esq. Registration No. 33,505

Respectfully submitted, LAHIVE & COCKFIELD, LLP

Elizabeth A. Hanley Registration No. 33,505



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Christine E. Seidman et al.

Serial No.: 10/788,779

Filed: February 27, 2004

For: Method For Detecting Disease Associated

Mutations

Attorney Docket No.: IGI-111CN2

Mail Stop Amendment Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450 Group Art Unit: 1634

Examiner: Not Yet Assigned

Certificate of First Class Mailing (37 CFR §1.8(a))

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Date of Signature and of Mail Deposit

Registration No. 33,506
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. The present application is a Continuation-in-Part of U.S. Serial No. 08/469,172, filed June 6, 1995 (Atty. Docket No. IGI-111CN). All references listed on the enclosed PTO Form SB/08 have been previously cited by or submitted to the

Serial Number: 10/788,779 Page -2- Group Art Unit: 1634

Office in the prior application, and, in accordance with 37 CFR §1.98(d), copies of the references are not enclosed but will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

Elizabeth A. Hanley, Esq. Registration No. 33,503

Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400

Date: _

GAD/EAH/MCA/les

Enclosures

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Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

Complete if Known				
Application Number	10/788,779			
Filing Date	February 27, 2004			
First Named Inventor	Seidman, Christine E.			
Art Unit	1634			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	IGI-111CN2			

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵
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		NON PATENT LITERATURE DOCUMENTS	
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	A1	Antonarakis, S.E., "Diagnosis of Genetic Disorders at the DNA Level", N.E. J. Med. 320(3):153-163 (1989)	
	A2	Chelly, J. et al., "Transcription of the Systrophin Gene in Human Muscle and Non-Muscle Tissues", <i>Nature</i> 333:858-860 (1988)	
	А3	Cotton, R.G., "Detection of Single Base Changes in Nucleic Acids", <i>Biochem. J.</i> 263:1-10 (1989)	
	A4	Epstein et al., "Differences in Clinical Expression of Hypertrophic Cardiomyopathy Associated with Two Distinct Mutations in the β-Myosin Heavy Chain Gene", <i>Clin. Invest.</i> 86(2):345-352 (1992)	
	A5	Geisterfer-Lowrance et al., "A Molecular Basis for Familial Hypertrophic Cardiomyopathy: A β Cardiac Myosin Heavy Chain Gene Missense Mutation", <i>Cell</i> 62:999-1006 (1993)	
	A6	Jarcho, J.A. et al., "Mapping a Gene for Familial Hypertrophic Cardiomyopathy to Chromosome 14q1", N.E. J. Med. 321:1372-1378 (1989)	
	Α7	Maron et al., "Patterns and Significance of Distribution of Left Ventricular Hypertrophy in Hypertrophic Cardiomyopathy", <i>Am. J. Cardiol.</i> 48:418-428 (1981)	
	A8	McKenna et al., "Echocardiographic Measurement of Right Ventricular Wall Thickness in Hypertrophic Cardiomyopathy: Relation to Clinical and Prognostic Features", <i>JACC</i> 11(2):351-358 (1988)	i i
	A9	Myers, R. et al., "Detection of Single Base Substitutions by Ribonuclease Cleavage at Mismatches in RNA:DNA Duplexes", <i>Science</i> 230:1242-1246 (1985)	

Examiner Date	
	1
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l s	STATEMENT BY APPLICANT			First Named Inventor	Seidman, Christine E.	
				Art Unit	1634	
	(Use as many si	heets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	2	Attorney Docket Number	IGI-111CN2	

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	B1	Roberts et al., "Direct Diagnosis of Carriers of Duchenne and Becker Muscular Dystrophy by Amplification of Lymphocyte RNA:, <i>The Lancet</i> 336:1523-1526 (1990)	
	B2	Rosenzweig, A. et al., "Preclinical Diagnosis of Familial Hypertrophic Cardiomyopathy by Genetic Analysis of Blood Lymphocytes", <i>N.E. J. Med.</i> 325:1753-1760 (1991)	
	ВЗ	Sarkar, G. et al., "Access to a Messenger RNA Sequence or Its Protein Product Is Not Limited by Tissue or Species Specificity", <i>Science</i> 244:331-334 (1989)	
	B4	Seidman, C. et al., "Mutations in Cardiac Myosin Heavy Chain Genes Cause Familial Hypertrophic Cardiomyopathy", <i>Mol. Biol. Med.</i> 8:159-166 (1991)	
	B5	Shapiro, L. et al., "Distribution of Left Ventricular Hypertrophy Cardiomyopathy: A Two Dimensional Echocardiographic Study", <i>JACC</i> 2(3):437-444 (1983)	
	B6	Solomon, S.D. et al., "Familial Hypertrophic Cardiomyopathy is a Genetically Heterogeneous Disease", <i>J. Clinic. Invest.</i> 86:993-999 (1990)	
	В7	Tanigawa, G. et al., "A Molecular Basis for Familial Hypertrophic Cardiomyopathy: An α/β Cardiac Myosin Heavy Chain Hybrid Gene", <i>Cell</i> 62:991-998 (1990)	
	B8	Watkins et al., "Characteristics and Prognosis Implications of Myosin Missense Mutations in Familial Hypertrophic Cardiomyopathy", <i>N. E. J. Med.</i> 326:1108-1114 (1992)	

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